

# Media Release

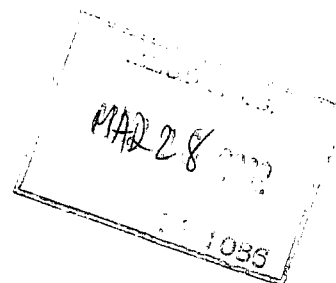
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Basel, 25 March 2002

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## Two innovative cancer drugs approved in Europe

- MabThera for the treatment of aggressive Non-Hodgkin's Lymphoma
- Xeloda and Xeloda in combination with Taxotere for breast cancer treatment

Roche announced today that its two anti-cancer drugs MabThera and Xeloda were approved by the European Medicines Evaluation Agency (EMA) for additional indications. Roche had received positive recommendation by the European authorities in mid-October last year for the innovative cancer treatments MabThera (for the treatment of aggressive Non-Hodgkin's Lymphoma) and Xeloda as well as Xeloda in combination with Taxotere (for the treatment of advanced breast cancer). This news comes just three days after the European authorities issued positive recommendations for Roche's Hepatitis C treatment Pegasys and the anti-influenza drug Tamiflu, as well as a label change for the weight management treatment Xenical.

"We are excited by our continued progress in Europe. With MabThera and Xeloda we are able to bring new hope to thousands of patients. MabThera can increase the chance of cure and prolong survival for patients with aggressive Non Hodgkin's Lymphoma, a rapidly fatal form of blood cancer. Xeloda is unique with its tumor-activated mechanism and is one of Roche's most significant new products, and we believe that Xeloda can help every woman who suffers from breast cancer cancer at some stage of her disease," said William M. Burns, Head of Roche's Pharmaceutical Division.

### About MabThera

The authorities approved the revolutionary anti-cancer medicine MabThera (rituximab), combined with standard chemotherapy, for treating an increasingly common form of blood cancer called aggressive non-Hodgkin's lymphoma (NHL). MabThera is already indicated for low-grade NHL in Europe.

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The EMEA's decision was based on results comparing MabThera plus standard chemotherapy (CHOP) with CHOP alone in a pivotal study. After analyzing the data available to date it is estimated that after two years of follow-up, 70% of patients will be alive with the MabThera plus CHOP combination, compared to 57% after standard chemotherapy alone. Current medical opinion indicates that if patients survive past the two-year milestone their chances of a cure can be up to 80%.

NHL affects approximately 1.5 million people around the world and is the 3<sup>rd</sup> fastest growing form of cancer behind melanoma of the skin and lung cancer. NHL is a more common form of blood cancer than leukaemia - approximately 55% of cases of NHL are categorised as aggressive and 45% indolent (a more slowly growing form of the disease). Until today's decision by the European authorities MabThera, Roche's second most successful product, has been indicated for relapsed or refractory indolent NHL only (low-grade NHL).

MabThera was discovered by IDEC Pharmaceuticals Corporation and was jointly developed with IDEC and Genentech, Inc. MabThera is Roche's second largest prescription product just four years after its first launch, with sales of more than CHF 1.6 million in 2001.

#### About Xeloda

The European Commission has granted marketing authorisation for Roche's anti-cancer tablet Xeloda (capecitabine) for the treatment of metastatic breast cancer. The Commission granted approval for two indications, Xeloda monotherapy after failure of intensive chemotherapy as well as combination of Xeloda with Taxotere after failure of anthracycline treatment. Xeloda/Taxotere is the first chemotherapy regimen to demonstrate a significant superior survival benefit compared to a standard treatment of Taxotere alone in patients with metastatic breast cancer, besides it showed tumour shrinkage and prevented tumour growth for longer compared with Taxotere alone.

The "smart tablet" Xeloda has a unique mechanism of action. It is activated by an enzyme, found at higher levels in cancer than in healthy tissue. This leads to more of the cancer-killing agent 5-FU being produced in the tumor, where it is needed. Taxotere further increases the levels of this enzyme, potentially leading to even more Xeloda being converted into cancer-killing 5-FU. Breast cancer is a primary cause of cancer-related deaths in women and the third leading cause of overall mortality. Almost 384,000 patients are newly diagnosed with breast cancer in Europe annually. About 50 percent of breast cancer patients develop metastatic disease after primary treatment and the average survival time for patients after diagnosis of metastatic disease is 18 to 30 months.

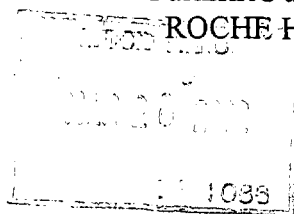
Xeloda/Taxotere for the treatment of patients with metastatic breast cancer is registered in the U.S., Canada and now in the European Union. As monotherapy, Xeloda is now registered in more than 70 countries worldwide for the treatment of metastatic breast cancer. Last year Roche received marketing authorisation for Xeloda in the treatment of metastatic colorectal cancer in most countries worldwide, including the United States and Europe. Xeloda development in additional cancer indications and in combination with other cancer treatments is ongoing. Last year Xeloda achieved sales over CHF 260 million.

#### **About Roche**

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-oriented healthcare groups in the fields of pharmaceuticals, diagnostics and vitamins. Roche's innovative products and services address needs for the prevention, diagnosis and treatment of disease, thus enhancing people's well-being and quality of life.

Roche is the world leader in Oncology. Its Franchise includes MabThera (non-Hodgkin's lymphoma), Xeloda (colorectal cancer, breast cancer), Herceptin (breast cancer), NeoRecormon (anaemia in various cancer settings), Roferon-A (leukaemia, Kaposi's sarcoma, malignant melanoma, renal cell carcinoma), Neupogen (neutropenia) and Kytril (chemotherapy and radiotherapy-induced nausea).

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Basel, 25 March 2002

## Roche Licenses Synthetic Erythropoiesis Protein from Gryphon Sciences

Roche and Gryphon Sciences (Gryphon), San Francisco, Calif., announced today that Roche has licensed all rights to Gryphon's Synthetic Erythropoiesis Protein (SEP), a synthetic protein made using Gryphon technology. SEP will be developed by Roche to treat the common conditions which cause anemia including the treatment of cancer with chemotherapy, and hemodialysis of patients suffering from chronic renal failure.

The drug, which has completed pre-clinical testing, has been shown to induce long lasting increases in the blood cell volume (hematocrit) of treated animals after only a single injection. The positive effects of treatment are long lasting and SEP appears to be safe and well tolerated. The drug is made using chemical protein synthesis to create the backbone of the molecule and incorporates well-defined polymers in order to increase the circulating half-life of the drug.

"This decision represents an important extension of our oncology and anemia portfolios and re-confirms our commitment to these therapeutic areas," comments Jonathan Knowles, Head of Global Pharma Research at Roche. "Patients affected by cancer or renal failure very often suffer from insufficient levels of red blood cells and SEP may become a major improvement for their therapy. Further, this agreement will strengthen our global position in this new generation of drugs for anemia. SEP is designed to be competitive with the very latest versions of anemia treatment."

Under the terms of the agreement, Roche will make up-front and milestone payments to Gryphon. Assuming all development milestones are achieved, the amount of this deal would be 155 million US dollars. Roche will also pay Gryphon royalties on product sales. Roche has received the exclusive, worldwide rights to develop, manufacture, market and sell SEP for all therapeutic indications. Further terms were not disclosed.

"Licensing our first synthetic protein drug to Roche is an important milestone for Gryphon", said Friedhelm Blobel, President and Chief Executive Officer of Gryphon Sciences. "This deal is an essential validation of our approach to producing a long list of performance-enhanced protein therapeutics."

#### **About Gryphon Sciences**

Gryphon Sciences produces protein therapeutics using two proprietary technologies. Gryphon's products combine chemically synthesized protein backbones with precision polymers to create potent therapeutics. The use of chemistry, rather than biology, allows the company to manipulate protein drugs in ways that were never before possible. Efficient-scalable processes with high yields make this a cost-effective way to manufacture valuable drugs. Gryphon Sciences is a private company located in South San Francisco, California. For more information visit [www.gryphonsci.com](http://www.gryphonsci.com).

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**This release appears in English only.**